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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,044	08/17/2005	Amit Krishna Antarkar	21281/0208272-US0	2710

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,044	ANTARKAR ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/10/09 was filed after the mailing date of the Specification on 8/15/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Claims 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the binary mixture of polymers" in lines 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the mixture of three polymers" in line 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lilliott et al (WO 01/35941 hereafter '941) in view of Hyon et al (USPN 5,100,669 hereafter '669) and Lui (EP 0 440 462 hereafter '462).

The '941 patent discloses a multilayered tablet and a process for making said tablet, wherein the tablet comprises a biguanide granulation compressed with a thiazolidinedione (abstract). The granulations comprise polymers and are combined, further treated with lubricants and compressed into tablets (Example 25 and 26). The biguanide includes metformin HCL in a concentration form 100-300 mg (pg 4, lin. 15-20) while the thiazolidinedione is present in concentrations from 2-12 mg (pg. 4, lin. 1-10). Each granulation comprises various polymers including hydroxypropylmethylcellulose, microcrystalline cellulose (pg. 3, lin. 22-25), guar gum, ethylcellulose, alginic acid, starch carboxymethylcellulose, and starch glycolate (pg. 7, lin. 15-pg.8, lin. 7), all common excipients in the tableting art. The metformin HCl granulation comprises at least 90% metformin and the thiazolidinedione comprises from 3.5-13.45% of its respective granulation (Examples 1-10). The granulations are prepared in traditional methods including wet granulation, the components are blended in a mixer, after which the granules are screened, dried, and passed through a filter before they are compressed into multilayered tablets (example 1-10). Each granulation comprises a mixture of polymers such as a mixture of PVP and HPMC in a ratio from 1:4 to 1:1.3 (Example 1). The granulation can comprise up to three polymers including microcrystalline cellulose, lactose and sodium starch glycolate (Example 5).

The reference is however silent to the particle size of the drug particles. The preparation of small particles of antidiabetic active agents prepared with excipients is well known in the art as seen in the '669 patent. The '669 patent discloses microparticles of various active agents including metformin and other antidiabetic compounds (col. 4, lin. 45-50). The particles are prepared with common excipients such as guar gum , starch, and gelatin (col. 5, lin. 15-20). The particles have a size from 0.1-300 microns, specifically 0.5-5 microns (abstract, Example 6). It would have been obvious to include these particles into the formulation of the '941 patent since they both comprising similar carrier compounds.

Regarding the release of the preparation it is the position of the Examiner that such limitations do not overcome the prior art since these limitations are functional limitation falling directly from the compositional components. The granulations and resulting multilayered tablets of the prior art comprising the same components combined in the same percentages, and as such would perform the same way under testing or in vivo. Applicant is reminded that a compound and its properties cannot be separated, as such the inherent properties of the composition of the instant claims would be found in the composition of the prior art since the compounds are the same.

Also the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. &

Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The reference is also silent to the specific viscosity of the carrier excipients, however the viscosity of the components in an inherent feature of the compound, and the inclusion of specific compounds based on the their specific viscosity is well known in the art as seen in the '462 patent. The '462 patent discloses a tablet formulation comprising a combination of hydroxypropyl celluloses ethers wherein the viscosities are either high or low (abstract). The high viscosities are above 3000 cps (pg. 3, lin. 5-35). The inclusion of these compounds helps to control the release of the active compounds (pg 2, lin. 55-58). It would have been obvious to include the high or low viscosity HPC ethers of the '462 in order to more precisely control the release of the active agents in the layers of the '941 patent.

With these things in mind it would have been obvious to combine the prior in order to more precisely control the release of the active agents in each layer. It would have been obvious to include the particles of the '669 patent into the formulation and method of the '941 patent since both patents disclose similar carrier formulation of microparticles of antidiabetic compounds. It would have been obvious to include the HPC ethers of the '462 patent in various viscosities in order to more precisely control the release of the active agents of the '941 patent. It would have been obvious to combine the prior art with an expected result of a stable multilayered tablet and a method of making such a tablet with activity to treat diabetes.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618